JUN 2 0 2007

Non-Confidential Summary of Safety and Effectiveness

14-Jun-07

Advanced Circulatory Systems, Inc.
7615 Golden Triangle Drive, Suite A Tel – 612-986-3917
Eden Prairie, MN 55344 Fax –952-942-8336

Official Contact: Keith Lurie, MD, Chief Medical Officer

Proprietary or Trade Name: CirQlator™ Intrathoracic Pressure Regulator

Common/Usual Name: Spirometer, therapeutic (incentive)

Classification Name: Spirometer, therapeutic (incentive)

Device: Intrathoracic Pressure Regulator (ITPR)

Predicate Devices: ResQPOD® Circulatory Enhancer - K022906, K033401
Bird Mark 8 ventilator – pre-amendment

Device Description:

The CirQlator™ is an intrathoracic pressure regulator intended to interface with the airway of a patient and a ventilation source. A vacuum source is connected to the ITPR that provides continuous low-level vacuum except when a positive pressure breath is given by a ventilation source, e.g. manual resuscitator. The applied vacuum decreases the intrathoracic pressure. When interposed between positive pressure ventilations, a decrease in intrathoracic pressure has been shown to increase vital organ perfusion and decrease intracranial pressure during states of shock, cardiac arrest, and other low blood flow states in animal studies.

Indications for Use:

Indicated Use - The CirQlator™ Intrathoracic Pressure Regulator is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation, as prescribed by a physician, licensed practitioner, or qualified technician. Recommended duration of use is up to four hours.

Patient Population - The CirQlator™ Intrathoracic Pressure Regulator may benefit people needing assisted ventilation that suffer from states of poor circulation, low blood pressure, or insufficient cardiac preload that may be reflected by low blood pressure. The device is not intended for those patients who would not benefit from an increase in cardiac preload.

Environment of Use - Hospital, pre-hospital (including EMS)

Contraindications - persons with pneumothorax;
persons with hemothorax;
persons who are hypertensive;
persons with uncontrolled bleeding.

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Performance testing:

Comparative bench testing was performed for the proposed device and the predicates and the performance features and functionality where found to be comparable.

In addition, animal testing was performed to demonstrate the proposed device performed as intended.

Comparison to Legally Marketed Predicate Devices:

The ITPR is viewed as substantially equivalent to the following predicate devices –

- ResQPOD Circulatory Enhancer (K022906, K033401)
- Bird Mark 8 respirator (pre-amendment)

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Circulatory Systems, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court # 102
Bonita Springs, Florida 34134-2015

JUN 20 2007

Re: K070490
Trade/Device Name: CirQlator™ Intrathoracic Pressure Regulator (ITPR)
Regulation Number: 21 CFR 868.5690
Regulation Name: Incentive Spirometer
Regulatory Class: II
Product Code: BWF, JOW
Dated: June 14, 2007
Received: June 15, 2007

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K070490 (To be assigned)

Device Name: CirQlator™ Intrathoracic Pressure Regulator (ITPR)

Indications for Use:

The CirQlator™ Intrathoracic Pressure Regulator is indicated for the temporary decrease in intrathoracic pressure to increase blood circulation, as prescribed by a physician, licensed practitioner, or qualified technician. Recommended duration of use is up to four hours.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K070490